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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,196	06/17/2000	Dana A. Haley	HYS-14	1768

7590 04/19/2002  
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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/19/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/596,196

Applicant(s)

HALEY ET AL.

Examiner

Holly Schnizer.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 11, 19, 20, 24-26 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 26 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 20, 24, 25 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicant's election with traverse of Invention II, Claims 10, 11, 20, 25, and 30 in Paper No. 7, filed February 6, 2002 is acknowledged. The traversal is on the ground(s) that SEQ ID NO:9 is found within SEQ ID NO:4. This argument is persuasive and both SEQ ID NO:4 and NO:9 are rejoined and are under examination. Applicants also urge that upon allowance of the product claims, claims drawn to methods of making and using the product should be rejoined under 37 CFR 1.141. This is not found persuasive because the method of making the product requires the use of a different product, that is, nucleic acid, which has not been searched. However, in accordance with *In re Ochiai*, Invention VI, Claim 24, has been rejoined with Invention II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 12-18, 21-23, and 27-29 have been canceled. Claims 19 and 26 have been withdrawn from further consideration because these claims are drawn to non-elected inventions. Note that Claim 26 has been amended to recite a polynucleotide (Invention I) sequence which is patentably distinct from the polypeptide as noted in the restriction requirement. Claims 10, 11, 19, 20, 24, 25, and 30 are currently under examination.

The formal drawing filed June 11, 2000 has been approved by the draftsman.

The disclosure is objected to because of the following informalities: The specification recites amino acids using the single letter code. 37 CFR 1.821 states that amino acids will be referred to in the 3 letter code.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 20, 24, 25, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 20, it is not clear what comprises a "kit", that is, aside from a composition of a polypeptide comprising SEQ ID NO:4 or the mature form thereof, what other items are in the kit? Are there instructions for use? A device for administration of the polypeptide? and so forth.

Claim 24 does not set forth a disease to be treated, nor an end points to the method of treatment. Therefore, the limitations of Claim 24 are indefinite.

In Claim 25, enzymes with leader sequences do not have activity; rather, it is when the leader or pro-sequences are cleaved that the mature form is activated. Therefore, it appears that SEQ ID NO:4 does not have activity, and Applicants may wish to amend Claim 25 to refer to only one or the other sequence, and add a new claim drawn to the remaining sequence. Additionally, the term "identical" is an absolute term. In the context of sequence comparison it is art-recognized to use the term "identity".

Claim 30 is confusing in that it is not clear what a polypeptide having "at least SEQ ID NO: 9" is.

It appears that the following amendments would place the claims in condition for allowance:

Cancel Claims 19 and 26. Non-elected.

Cancel Claim 20. The specification does not appear to describe the contents of a kit.

Claim 24. A method of [treatment] treating wounds by increasing coagulation, said method comprising administering to a mammalian subject [in need thereof] having a wound a therapeutic amount of a composition comprising a polypeptide of Claim 10 and a pharmaceutically acceptable carrier, wherein said wound is healed.

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Claim 25. An isolated polypeptide having prothrombinase activity comprising an amino acid sequence which is at least 99% [identical] identity to the amino acid sequence of SEQ ID NO: [4 or] 9.

Claim 31 (new). An isolated polypeptide having at least 99% identity to the amino acid sequence of SEQ ID NO: 4, wherein the mature form of said polypeptide has prothrombinase activity.

Claim 30 should read: An isolated polypeptide comprising SEQ ID NO:9, wherein said polypeptide has prothrombinase activity.

Claims 10 and 11 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is 703-305-3722.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

kcc  
April 18, 2002